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U.S. APPLICATION NO.

09/807462

FIRST NAMED APPLICANT

ATTY. DOCKET NO.

B

550750 -185

INTERNATIONAL APPLICATION NO.

PCT/US99/24554

RAYMOND J LILLIE  
CARELLA BYRNE BAIN G  
STEWART & OLSTEIN  
6 BECKER FARM ROAD  
ROSELAND, NJ 07068

FILLAN CECCHI

I.A. FILING DATE

PRIORITY DATE

20 OCT 99

21 OCT 98

DATE MAILED:

07 MAY 2001

### NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

1. The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as ☐ a Designated Office (37 CFR 1.494) ☒ an Elected Office (37 CFR 1.495):

- ☒ U.S. Basic National Fee. ☒ Indication of Small Entity Status.  
☒ Copy of the international application. ☐ Translation of the international application into English.  
☒ Oath or Declaration of inventor(s). ☐ Translation of Article 19 amendments into English.  
☐ Copy of Article 19 amendments. ☐ Other:  
☐ Priority Document.  
☒ The International Preliminary Examination Report in English and its Annexes, if any.  
☐ Translation of Annexes to the International Preliminary Examination Report into English.

2. ☒ Applicant has requested early processing under 35 U.S.C. 371(f) but has not filed the following indicated items and/or the indicated items in paragraph 3 below. The Basic National Fee and the copy of the international application must be filed prior to 20 or 30 months from the priority date to avoid abandonment.

- ☐ U.S. Basic National Fee. ☐ Copy of the international application.

3. The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- ☐ a. Translation of the application into English. A processing fee will be required if submitted later than the appropriate 20 or 30 months from the priority date.  
☐ The current translation is defective for the reasons indicated on the attached Notice of Defective Translation.  
☐ b. Processing fee for providing the translation of the application and/or the Annexes later than the appropriate 20 or 30 months from the priority date (37 CFR 1.492(f)).  
☐ c. Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), properly identifying the application (preferably by the international application number and international filing date). A surcharge will be required if submitted later than the appropriate 20 or 30 months from the priority date.  
☒ The current oath or declaration does not comply with 37 CFR 1.497(a) and (b) for the reasons indicated on the attached PCT/DO/EO/917.  
☒ d. Surcharge for providing the oath or declaration later than the appropriate 20 or 30 months from the priority date (37 CFR 1.492(e)).

4. Additional claim fees of \$ \_\_\_\_\_ as a ☐ large entity ☐ small entity, including any required multiple dependent claim fee, are required. Applicant must submit the additional claim fees or cancel the additional claims for which fees are due (37 CFR 1.492(g)). See attached PTO-875.

5. ☐ Applicant has not submitted the required sequence listing pursuant to 37 CFR 1.821-1.825. See attached PCT/DO/EO/920.

**ALL OF THE ITEMS SET FORTH IN 3(a)-3(d), 4 AND 5 ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 22 OR 32 MONTHS (where 37 CFR 1.495 applies) FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.**

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

6. If box 3a or 3c is checked, a translation of the Annexes **MUST** be submitted no later than the time period set above or the Annexes will be cancelled. A processing fee will be required if submitted later than 20 or 30 months from the priority date.

7. ☐ The Article 19 amendments are cancelled since a translation was not provided by the appropriate 20 (37 CFR 1.494(d)) or 30 (37 CFR 1.495(d)) months from the priority date.

Applicant is reminded that any communication to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above. (37 CFR 1.5)

**A copy of this notice MUST be returned with this response.**

Enclosed: ☒ PCT/DO/EO/917☐ Notice of Defective Translation☐ PTO-875☐ PCT/DO/EO/920Karen Williams *KW*

BPM PCT/DO/EO/917 (March 2001)

Telephone: 703.295.3688

Document2

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OPERATOR: LK

TIME COMPLETED: \_\_\_\_\_

EXT. NO.: 527DATE: October 1, 2001OUR FILE NO.: 550750-185

NAME

FIRM:

FAX NO.

Karen Williams

U.S. Patent and Trademark Office

703-305-3230

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04 OCT 2001

Legal Staff  
International DivisionFROM: Raymond J. LillieTotal Pages Included Transmittal Sheet: 14

COMMENTS:

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Applicant(s): Burnside, et al

Serial No.: 091807,462 Filed: April 11, 2001  
 Title (or mark): Oral Pulsed Dose Drug Delivery System

### DOCUMENTS ENCLOSED

☐ Application sheets: Descr.: \_\_\_\_\_

Drawing sheets: \_\_\_\_\_

☒ Declaration (executed 7/2/01, 6/25/01, 7/10/01, 7/11/01,  
6/5/01, 7/3/01, 6/18/01,  
6/4/01.

☐ Verified Statement Claiming Small Entity Status

☐ Response to OA dated \_\_\_\_\_

☐ \_\_\_\_\_ Mo. Ext. of Time

☒ Other Application Transmittal Letter;  
Copy of Notification of Missing Requirements

☐ Formal Drawing \_\_\_\_\_ sheets

First class mail

Certificate Dated: \_\_\_\_\_

Docket No.: 550250-185

Claims \_\_\_\_\_ Abstract \_\_\_\_\_

☐ Formal

☐ Informal

☒ Assignment to Shire Laboratories, Inc.

☐ Type of OA: \_\_\_\_\_

☐ Inform. Discl. Statement

☒ Petition for Extension of Time  
(1 month sm enty)

☒ Check Amount \$ 160.00 No. \_\_\_\_\_

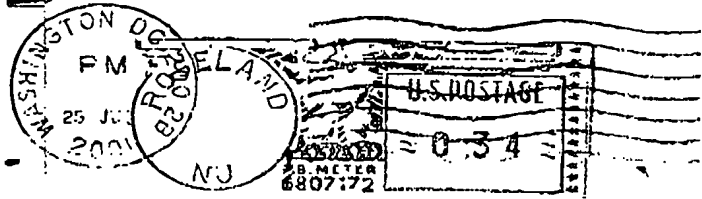
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**CARELLA, BYRNE, BAIN, GILFILLAN  
CECCHI, STEWART & OLSTEIN, P.A.**  
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Roseland, New Jersey 07068

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Carella Byrne, Bain, Gillman, Cecchi, Stewart & Olstein P.A.  
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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

**Patent Examining Operations**

Application of: Burnside, et al.  
Serial No: 09/807,462 Art Unit: Not Assigned  
Filed: April 11, 2001 Examiner: Not assigned  
Title: Oral Pulsed Dose Drug Delivery System  
Attorney  
Docket No.: 550750-185

**TRANSMITTAL LETTER**

Box Assignments  
Commissioner for Patents  
Washington, D.C. 20231

Dear Sir:

Enclosed please find the following:

1. Executed Declaration and Power of Attorney;
2. Assignment;
3. Assignment Recordation form;
4. Petition for Extension of Time (1 month small entity);
5. Copy of Notification of Missing Requirements;
6. Check No. \_\_\_\_\_ in the amount of \$ 160.00; and
7. A self-addressed, postage paid, return receipt postcard, date stamp and return of which is respectfully requested.

The Commissioner is authorized to charge payment of any additional filing fees required under 37 C.F.R. 1.16 associated with this communication or credit any overpayment to Deposit Account No. 03-0678.

**FIRST CLASS CERTIFICATE**

I hereby certify that this correspondence is being deposited today with the U.S. Postal Service as First Class Mail in an envelope addressed to: Box Assignment  
Assistant Commissioner for Patents  
Washington, D.C. 20231

*Raymond J. Lillie* 7/19/01  
Raymond J. Lillie, Esq. Date

Respectfully submitted,

*Raymond J. Lillie*  
Raymond J. Lillie, Esq.  
Reg. No. 31,778

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